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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/089,700 | 01/09/2003 | Robert Paul Anderson | HO-P02416USO | 2705 |
| 34141 | 7590 | 12/29/2004 | EXAMINER | |
| COZEN O' CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508 | | | SAUNDERS, DAVID A | |
| | | | ART UNIT | PAPER NUMBER |

1644

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

089,700

Applicant(s)

ANDERSON et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 9/13/04
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 112-163 is/are pending in the application.
- Of the above claim(s) 120-122, 124-127, 132-135, 139-142, 152-163 is/are withdrawn from consideration.
- ☒ Claim(s) 112-115, 123 is/are allowed.
- ☒ Claim(s) 116-119, 128-131, 138, 143-151 is/are rejected.
- ☒ Claim(s) 136-137 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Art Unit: 1616

The amendment of 9/13/04 has been entered. Claims 112-163 are pending.

Applicant's election with traverse of Group IX (claims 112-119) in the reply filed on 9/13/04 is acknowledged. The traversal is on the ground(s) that unity of invention exists by virtue of applicant's recognition of an epitope at positions 62-68 of gliadin, and that the claims do not encompass natural gliadins. This is not found persuasive because the recognition that an epitopic region is present at residues 62-68 of gliadin is merely an intellectual concept. What must be considered is that applicant is claiming distinct products having different uses that, while being related to this region, nevertheless require different searches? It is noted that SEQ ID NO: 1 and 2 of instant claims 112-119 have an E residue at position 65 of this epitopic region. As the examiner understands the disclosure, it is the presence of these E residues that renders the peptides of SEQ ID NO: 1 and 2 capable of inducing a T-cell response. On the other hand, the mutant gliadin proteins of Group X do not have any E recited at this position and, in fact, have numerous residues other than E recited in claim 121, these peptides are claimed as having a "decreased ability... to induce a T-cell response" (claim 121, part a). It is clear, also, that the peptides of claims 112-119 versus those of 120-121 do not have a common core structure in the epitope; the former have the critical E residue, while the latter do not; also the peptides of claims 112-119 and of 120-121 have different uses – e.g. the former can be used in diagnostic assays for sensitivity to food products, while the latter could be part of a food product having reducing allergenicity.

Art Unit: 1616

Since the peptide products of claims 112-119 versus those of claims 120-121 have no common core structure and have critically different immunogenic properties that confer different uses of the products, there is no unity of invention. Applicant is reminded that unity of invention involves one product and the first recited use thereof.

The requirement is still deemed proper and is therefore made FINAL.

The examiner will examine elected claims 112-119 as well as claims 123 and 128-131, which also pertain to polypeptides containing SEQ ID NO: 1 and/or 2.

The examiner will also examine claims 136-138 to a kit containing the peptide, but without dependency from non-elected claim 120.

The examiner will also examine claims 143-151 pertaining to diagnostic uses of the peptide, however without dependency from non-elected claim 120.

Claims 112-119, 123, 128-131, 136-138 and 143-151 are thus under examination.

Claims 115, 128-131, 138 and 144 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 115, claim 128 at lines 8-9, and claim 129 at lines 9-10 are confusing by reciting "a peptide of 7-50 amino acids" and "SEQ ID NO: 2" because SEQ ID NO: 2 is longer than 7 amino acids.

In claim 129, line 118 recitation of "wherein" appears to be surplusage.

Claim 129 is confusing as to whether a composition" (line 1) or a "product" (line 22) is being claimed. Note that the latter lacks antecedent basis.

In claim 138 "the antibody IFN. Gamma. Complex" lacks antecedent basis.

Claim 144 is confusing because the peptide is administered to the skin. There is thus no obtaining of a "sample" to be used in step a) of base claim 143 and no "determining in vitro" as required in step b) of claim 143.

Claims 116-119 and 128-131 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the invention. The claims recite new matter.

Firstly claims 116-118 contain new matter by reciting "and other/gliadin/non-gliadin sequence" without limiting the other sequence to one that is fused, as in dependent claim 119. The examiner only finds fusion proteins and not other kinds of polypeptides (e.g. conjugates of SEQ ID NO: 1 and another peptide) described at page 10, line 15; page 22, line 10).

Secondly, the examiner finds no description for the fusion of SEQ ID NO: 1 to another gliadin sequence, as in claims 116-117 and in claim 128, lines 2-15 and claim 129, lines 3-17. The examiner only finds support for fusion of SEQ ID NO: 1 to a non-gliadin sequence (page 10, lines 15-17). In the case where there is fusion to another gliadin sequence (or more than one thereof), it appears that the fusion is of a mutated form of the disclosed sequences (e.g. SEQ ID NO: 1 of

Art Unit: 1616

2) to the gliadin sequence. See page 22, lines 3-12. Applicant is thus claiming more embodiments than originally disclosed.

Claims 116-117 and 128-131 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has not disclosed how to use the invention in which SEQ ID NO: 1 or 2 is fused to another gliadin sequence.

As noted supra, under the 112 new matter rejection, it appears that applicant only disclosed the making and using of a mutated form of SEQ ID NOS: 1 or 2 to another gliadin sequence. One thus does not know whether the instantly claimed fusion polypeptides are to be used in diagnostic testing, in immunizing, or in tolerizing treatments.

Claims 143-151 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 143, 144 and 151 contain new matter by virtue of reciting "animal".

Applicant considers that original claims 1, 5 and 13 support instant claims 143, 144 and 151, respectively. The examiner notes that the original claims recite "individual" and that the specification defines an "individual" as a human

Art Unit: 1616

(page 5, lines 30-31). Applicant's new claims have thus improperly broadened the scope of the claimed invention.

The claims under examination are given benefit of the 01 OCT. 1999 filing date of priority document GB 9923306.6. All examined claims are allowable over the prior art of record.

Claims 136-137 are objected to as depending from non-elected claim 120. Note that rejected claims 143 and 151 also depend from non-elected claim 120.

On attached form PTO-1449 reference G has been deleted because the examiner did not find it in the IFW contents. This reference has been considered and cited on attached form PTO 892.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (571) 272-0849. The examiner can normally be reached on Tuesday through Friday 8 AM to 5:30 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/LR
December 15, 2004


DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644